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No. 08-1021

IN THE

Supreme Court of the United States

GILEAD SCIENCES, INC., *et al.*,
Petitioners,

v.

TRENT ST. CLARE, *et al.*,
Respondents.

On Petition for a Writ of Certiorari To the United States Court of Appeals For the Ninth Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

Whether a plaintiff in a "fraud on the market" case under Section 10(b) of the Securities Exchange Act must plead facts with sufficient particularity to support a reasonable, non-speculative belief that the plaintiff can ultimately prove loss causation.

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BRIEF OF WASHINGTON LEGAL FOUNDATION AS AMICUS CURIAE IN SUPPORT OF PETITIONERS

INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF) is a non-profit public interest law and policy center with supporters in all 50 States.[1] WLF devotes a substantial portion of its resources to defending free-enterprise, individual rights, and a limited and accountable government.

To that end, WLF has appeared before this and other federal courts in numerous cases raising issues relating to the proper scope of the federal securities laws. *See, e.g., Stoneridge Inv. Partners, LLC v. Scientific Atlanta, Inc.*, 128 S. Ct. 761 (2008); *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499 (2007); *Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Dabit*, 547 U.S. 71 (2006); *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336 (2005).

WLF also has participated extensively in litigation in support of its view that off-label use of FDA-approved products by licensed physicians is an important component of optimal health care and ought not to be restricted unnecessarily. WLF successfully challenged the constitutionality of certain FDA

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[1] Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, made a monetary contribution intended to fund the preparation and submission of this brief. More than ten days prior to the due date, counsel for WLF provided counsel for Respondents with notice of its intent to file this brief.

restrictions on speech about off-label uses and has in place a permanent injunction against enforcement of those restrictions. *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000).

WLF is concerned that the Ninth Circuit's decision essentially eliminates the "loss causation" requirement as a check on frivolous securities litigation alleging stock fraud. If Respondents' complaint is deemed sufficient to withstand a motion to dismiss despite failing to supply any facts that would render plausible their claim that their losses were caused by Petitioners' alleged material misrepresentations, few if any securities fraud complaints would be subject to dismissal at the pleadings stage. WLF does not believe that the Ninth Circuit's overly lenient pleadings standard is faithful to Congress's intent when it adopted the Private Securities Litigation Reform Act of 1995 (PSLRA), Pub. L. No. 104-67, 109 Stat. 737.

WLF is filing this brief because of its interest in the fair adjudication of lawsuits raising securities law issues; it has no interest, financial or other, in the outcome of this lawsuit. Because of its lack of direct economic interests, WLF believes that it can assist the Court by providing a perspective that is distinct from that of any party. WLF is filing its brief with the consent of all parties; letters of consent have been lodged with the Court.

STATEMENT OF THE CASE

This case raises important issues regarding the

circumstances under which a complaint alleging securities fraud is subject to dismissal under Fed.R.Civ.P. 12(b)(6) for failure to adequately allege "loss causation." The Ninth Circuit held that a plaintiff adequately alleges loss causation so long as he alleges facts to support a not "facially implausible" theory regarding how the defendant's alleged misrepresentation caused the plaintiff's loss. Pet. App. 17a. If the not-facially-implausible standard is met, then "the court's skepticism is best reserved for later stages of the proceedings." *Id.*

Respondents are several individuals who allege that they suffered losses after purchasing shares of Petitioner Gilead Sciences, Inc. in reliance on material misrepresentations regarding Gilead's financial condition. If Respondents really did lose money from their investment in Gilead, they are among a very small handful of investors who suffered that fate. The performance of Gilead common stock has been nothing short of spectacular during the past decade. Attached as Appendix A is a chart showing the price of Gilead common stock from January 1, 2002 to March 13, 2009. During that period, the stock has appreciated in value more than 400% – even taking into account the sharp decline experienced by almost all equities since September 2008. While, as is true of all publicly traded stock, Gilead has had some up-and-down fluctuations, Gilead's downward fluctuations have been far less pronounced than those for most other stocks. Indeed, as the chart demonstrates, the October 29, 2003 downward fluctuation that is the subject of this lawsuit was extremely short-lived; the stock regained all of its lost value by December 2, less than five weeks later. The

chart also demonstrates Gilead's consistent stock appreciation; the value of Gilead common stock was greater on December 31 of every year during this decade than it was on the preceding December 31. Investors who purchased Gilead stock during the class period applicable to this lawsuit (July 14 to October 28, 2003) and who held on to their stock would have more than tripled their investments.

Petitioner Gilead is a biopharmaceutical company that discovers, develops, and commercializes therapeutics for the care of patients with life-threatening diseases.[2] Viread, an anti-retroviral drug used to treat HIV/AIDS, has been Gilead's best-selling product since its introduction in 2001. Respondents allege that in 2001-2003 Gilead engaged in a campaign to promote Viread for HIV/AIDS treatments for which the federal Food and Drug Administration (FDA) had not approved the drug. They allege that Gilead materially misrepresented the company's financial condition by failing to disclose this allegedly illegal marketing campaign; they allege that the value of Gilead stock was inflated by this omission, which led to overestimations of future sales of Viread.

On August 7, 2003, FDA released a Warning Letter that it had sent to Gilead the previous month; the letter stated that FDA considered certain oral representations made by a Gilead representative at a promotional booth in April 2003 to be improper. The market did not react negatively to the Warning Letter,

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[2] Other Petitioners were officers of Gilead in 2003. All Petitioners are referred to herein collectively as "Gilead."

but Respondents allege that individual doctors did react negatively. They allegedly reacted by writing fewer Viread prescriptions than they would have written but for the Warning Letter.

On October 28, 2003, Gilead announced its financial results for the third quarter of 2003. Those results included a significant drop in reported Viread sales during the third quarter. The next day, Viread common stock dropped 12% in value. Respondents allege that the drop was caused by the disclosure (on August 7) that FDA had issued a Warning Letter alleging that Gilead had been engaged in i mproper promotion of Viread. According to Respondents, the chain of causation worked as follows: (1) disclosure of the Warning Letter caused physicians to be more reluctant to prescribe Viread than they otherwise would have been; (2) although that reluctance led to reduced Viread sales, the market was generally unaware at first of the Warning Letter's impact on sales; (3) on October 28, the market finally became aware that the Warning Letter was having a huge impact on sales – indeed, according to Respondents, much of the announced sales decrease was attributable to physicians' reluctance to write Viread prescriptions after learning of the Warning Letter; and (4) once investors fully understood the significant impact the Warning Letter was likely to have on future sales of Viread, Gilead stock dropped on October 29, 2003.

There are a number of uncontested facts that throw into considerable doubt Respondent's explanation for the October 28 financial results and the October 29 drop in the price of Gilead stock.. First, analysts at the

time all attributed the sales drop to inventory build-up (by the three wholesalers who purchase almost all of the products sold by Gilead). Analysts concluded that Gilead's sales dropped not as a result of a decrease in prescriptions being written for Viread, but because wholesalers during the third quarter were drawing down the inventory they had built up during the second quarter in anticipation of a previously announced June 2003 price increase for Viread.[3] The evidence indicates that the number of Viread prescriptions being written by doctors increased during the third quarter.

Second, there was virtually no discussion of FDA's Warning Letter in the days leading up to the October 29 price drop. The market did not react at all to the initial disclosure of the Warning Letter, which alleged that a single Gilead official had engaged in improper promotion of Viread on a single occasion. Respondents allege that Gilead's misconduct was far more widespread than the single incident that was the subject of the Warning Letter and that Gilead had misleadingly omitted mention of that misconduct. If so, there is no evidence to suggest that investors by October 29, 2003 had become aware of the allegedly widespread misconduct.

Third, although Gilead stock dropped 12% on October 29, it immediately started to recover and by December 2, 2003 had returned to its October 28 price. Respondents have failed to provide any plausible

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[3] Analysts explained that third quarter Viread sales were lower than anticipated because the second-quarter inventory build-up had been larger than analysts had originally anticipated.

explanation for that rapid increase in value. If, as Respondents allege, the market was finally aware by October 29 that a significant portion of Viread sales were being driven by Gilead's improper promotional activities and that the failure to disclose those activities had led to Gilead common stock being overpriced, there is no plausible explanation for the rapid subsequent price rise. There is no reason to believe that market participants suddenly forgot that the stock had previously been overpriced.

Respondent's suit, filed within weeks of the October 29, 2003 price drop, alleged violations of §§ 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b) & 78t(a), and SEC Rule 10b-5. The district court dismissed various versions of the complaint on three occasions under Rule 12(b)(6) for failure to adequately allege loss causation.

On the third occasion, in May 2006, the court dismissed the complaint with prejudice. Pet. App. 21a-41a. The court concluded that the connection between the FDA Warning Letter (released on August 7, 2008) and the drop in Gilead stock price nearly three months later was too attenuated to support a loss causation argument. *Id.* at 35a. The court found that the Warning Letter did not cause analysts to predict a decrease in Viread sales; to the contrary, in October and November 2003 analysts predicted that sales would continue to grow. The court deemed such predictions an indication that even after October 28 the market attached little significance to the Warning Letter. *Id.* at 36a. The court also faulted Respondents for failing to plead facts suggesting either that Gilead's failure to

disclose an off-label marketing scheme had inflated the price of Gilead stock or that the publication of the FDA Warning Letter had led practitioners to materially decrease their demand for Viread. *Id.* at 38a n.12.

The Ninth Circuit reversed and remanded. Pet. App. 1a-20a. The court held that a complaint in a securities fraud suit is not subject to rule 12(b)(6) dismissal so long as it pleads "enough facts to state a claim to relief that is plausible on its face." *Id.* at 12a. The court said that the complaint had alleged a plausible theory explaining how the October 29 stock price drop was caused by the Warning Letter issued months earlier. *Id.* at 19a. The court held that a "limited temporal gap" between the time that a misrepresentation is revealed and the subsequent decline in stock price "does not render a plaintiff's theory of loss causation per se implausible." *Id.*

The appeals court concluded that this Court's loss causation ruling in *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336 (2005), is inapplicable to cases, as here, in which the plaintiff can point to a drop in stock value that occurs after the alleged misrepresentation is revealed. *Id.* at 15a. The appeals court did not acknowledge the possibility that there might have been other factors that led to the October 29 price drop, nor did it discuss whether the complaint adequately explained why the price drop should be attributed to the disclosure of the Warning Letter and not to some other cause. Nor did it discuss whether Respondent's theory of causation was consistent with the rapid rise of Gilead's stock in the days following October 29. The appeals court indicated that if a district court is

skeptical of a plaintiff's loss causation theory, that "skepticism is best reserved for later stages of the proceedings when the plaintiff's case can be rejected on evidentiary grounds." *Id.* at 17a.

REASONS FOR GRANTING THE PETITION

The petition raises issues of exceptional importance. When it included a provision in the PSLRA that explicitly made "loss causation" an element of any Section 10(b) securities fraud case, Congress made clear that it intended the courts to weed out at the pleadings stage complaints that failed to adequately allege loss causation. Congress did so because it realized that defending even frivolous securities fraud cases can be extremely burdensome, and that those burdens effectively require public companies to settle any case that they cannot dispose of on the pleadings.

The Court in *Dura* recognized the importance of the loss causation requirement as an important pleadings-stage screening device that allows courts to weed out non-meritorious securities law claims. Yet, if the standard adopted by the Ninth Circuit is upheld, virtually any complaint alleging securities fraud can survive a loss causation standard. Under that standard, all a plaintiff need do to avoid dismissal on the pleadings is to avoid the mistake made by the *Dura* plaintiffs – make sure that the complaint alleges that the defendant's alleged misrepresentation became known to the market *before* the defendant's stock price dropped (not afterwards, as in *Dura*). Under the Ninth Circuit standard, it apparently does not matter that (as here) there is no real evidence that the market ever became

aware of the alleged misrepresentation (or even that there ever was a misrepresentation); a plaintiff can survive a loss-causation motion to dismiss by merely alleging that such a disclosure occurred and, assuming the truth of that allegation, by demonstrating that it is "plausible" that such a disclosure might have caused a drop in the defendant's stock price. According to the Ninth Circuit, any more exacting review of the loss causation issue must await a summary judgment motion and/or trial – after the completion of discovery.

As the Petition amply demonstrates, the Ninth Circuit's "plausible on its face" standard is inconsistent with the standard applied by every other federal appeals court in judging motions to dismiss securities fraud complaints. That standard also conflicts with the loss causation standard set forth in *Dura*. Review is warranted to resolve those conflicts.

WLF writes separately to explain why the Ninth Circuit's standard is toothless and will allow plaintiffs' attorneys to craft complaints that can virtually always survive Rule 12(b)(6) motions to dismiss. Such a toothless standard is inconsistent with Congress's intent in adopting the PSLRA, which was designed to ensure that complaints will be dismissed at the pleadings stage unless they provide factual allegations that explain how the plaintiffs' losses were caused by the defendants' alleged misrepresentations. Under the Ninth Circuit's standard, there will be no such dismissals.

Review is also warranted because it is particularly onerous for companies, such as Gilead, whose activities are subject to close federal regulation. The Ninth

Circuit's standard permits plaintiffs to transform virtually any regulatory infraction into a securities fraud case; all they need do is locate a stock price drop that followed disclosure of the infraction, and then allege that the disclosure caused the price drop. This Court in *Stoneridge* warned against permitting use of the securities laws to police a broad range of business activities having little or no connection to the purchase or sale of securities.

Review is also warranted because the pleading standard adopted by the Ninth Circuit is particularly onerous on life-science companies such as Gilead and other relatively new and small companies that are capital intensive. Such companies are particularly prone to being sued for securities fraud because their stock prices tend to be more volatile than are the stock prices of more established public companies. At the same time, such companies tend to be more disrupted by such suits and simply cannot afford to allow the suits to continue if they cannot win dismissal on the pleadings. Yet, the Ninth Circuit's lenient standard will virtually always prevent them from winning dismissal by demonstrating absence of loss causation.

Indeed, this case is a poster child for abusive and frivolous securities fraud litigation. It is very difficult to imagine that there are more than a handful of investors who ever lost money by investing in Gilead common stock. The stock price has been on a virtually unbroken upward trajectory for more than a decade. The October 29, 2003 drop in stock price that is the subject of this lawsuit persisted for less than five weeks, and the initial complaint filed in this very complaint

provides a very plausible explanation (an under-estimation of wholesalers' inventory levels) for that temporary blip. Respondents' far-fetched, alternative explanation for the temporary price drop should be laughed out of court. Instead, it survived the Ninth Circuit's loss causation standard with flying colors – thereby highlighting the need for immediate review of that standard.

I. Review Is Warranted Because the Ninth Circuit's Standard Prevents Securities Fraud Defendants From Obtaining Dismissal on the Pleadings, Contrary to Congress's Intent in Adopting the PSLRA

Congress adopted the PSLRA in 1996 in an effort to eliminate what it viewed as abuses of the securities laws by plaintiffs' lawyers. *Dura*, 544 U.S. at 347. Those "'abusive'" practices included "'the routine filing of lawsuits . . . with only [a] faint hope that the discovery process might lead eventually to some cause of action.'" *Id.* (quoting H.R. Conf. Rep. No. 104-369 p.31 (1995)). While recognizing the need to permit plaintiffs to file complaints without undertaking a "great burden," the Court recognized that "allowing a plaintiff to forgo giving any indication of the economic loss and proximate cause that the plaintiff has in mind would bring about harm of the very sort the statutes seek to avoid." *Id.* The Court explained that relaxing rules requiring the plaintiff to plead facts demonstrating loss causation:

> [W]ould permit a plaintiff 'with a largely groundless claim to simply take up the time of a

> number of other people, with the right to do so representing an *in terrorem* increment of the settlement value, rather than a reasonably founded hope that the [discovery] process will reveal relevant evidence.' . . . Such a rule would tend to transform a private securities action into a partial downside insurance policy.

Id. at 347-48 (quoting *Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 741 (1975)).

Although the private damage action for violation of § 10(b) of the Securities Exchange Act of 1934 is judicially implied, *Dura* recognized that Congress imposed explicit statutory limits on that right of action when it adopted 15 U.S.C. § 78u-4(b) in 1996 as part of the PSLRA. *Dura*, 544 U.S. at 341. In particular, § 78u-4(b)(4) adds an explicit loss-causation requirement to securities fraud actions: "the plaintiff shall have the burden of proving that the act or omission of the defendant alleged to violate this title caused the loss for which the plaintiff seeks to recover damages."

Dura said that it was unnecessary to decide the precise standard for judging the adequacy of a complaint's loss causation allegations, because even under the most lenient standard – the "fair notice" standard set forth in Fed.R.Civ.P. 8(a)(2) – the plaintiff in that case had failed to allege loss causation adequately. *Dura*, 544 U.S. at 346. The plaintiffs had alleged that the defendant's misrepresentations had caused the plaintiffs to purchased stock at an inflated value. But the Court held that such an allegation is insufficient to allege loss causation, because the

plaintiffs suffered no loss so long as the stock's value was still inflated. *Id.* at 342. Rather, to show loss causation, the plaintiff would have to show that the misrepresentation was later revealed to the market and that the revelation caused a subsequent decrease in stock price. *Id.* at 342-43. Because the plaintiff had not alleged that the misrepresentation had been revealed until after the plaintiffs' stock had declined in value, the Court held that they had failed adequately to allege loss causation. *Id.* at 346-47.

The Ninth Circuit latched onto that one aspect of *Dura* (the reverse order of the stock price decrease and the revelation of the defendant's alleged misrepresentations) and concluded that a plaintiff *always* meets the loss causation pleading requirement by showing that the alleged revelation of the misrepresentation was followed without too much lapse of time by a drop of the defendant's stock price. Pet. App. 19a. The plaintiffs' bald allegation that the revelation "caused" the price drop is sufficient to meet the loss causation pleading standard, the Ninth Circuit held, so long as the complaint pleads "enough facts to state a claim for relief that is plausible on its face." *Id.* at 12a.[4]

That lenient standard essentially does away with the loss causation requirement at the pleadings stage. It provides a road map to any enterprising plaintiffs'

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[4] The Ninth Circuit used the word "plausible" throughout its decision, *see e.g.*, Pet. App. 12a, 17, 18a, 19a, thereby indicating that it was applying a standard roughly akin to the Rule 8(b) notice pleading standard, rather than the stricter pleading standard advocated by Gilead and adopted by each of the other federal appeals courts that has considered the issue.

attorney seeking to file a securities fraud lawsuit following a drop in a company's stock price caused by an earnings report that disappointed some investors. All that the attorney would need to do would be to scour the company's public statements in the months preceding the price drop to find something that could be deemed a misrepresentation. Under the Ninth Circuit's standard, it would then be sufficient to survive a motion to dismiss to allege that the disappointing earnings report constituted the necessary disclosure to the market of the misrepresentation and that the stock had previously been overpriced due to the misrepresentation. Never mind that (as here) there was no public discussion of the alleged misrepresentation at the time of the price drop and that there were other, far more plausible explanations for the drop. It is sufficient, under the Ninth Circuit's standard, to assert that the price drop was an indication that the market finally understood the significance of the prior misrepresentation and was readjusting the stock price accordingly; any issues regarding the accuracy of the claimed causal connection should be deferred until the summary judgment stage, after discovery has been completed. Pet. App. 17a.

That understanding of the loss causation requirement cannot be squared with congressional intent in adopting the PSLRA. One of the purposes of that statute was to ensure that public companies would have the opportunity to win dismissal of insubstantial securities fraud cases at the pleadings stage. *See, e.g.*, H.R. Conf. Rep. No. 104-369, at 44 (1995), *reprinted in* 1995 U.S. Code Cong. & Admin. News 730. The reason that Congress deemed the availability of early dismissals

as critical to the PSLRA's goals is clear: Congress realized that security fraud suits, while often lacking in merit, become too expensive for companies to litigate if the complaint survives a motion to dismiss and huge discovery costs (*e.g.*, costs associated with subjecting senior executives to lengthy depositions) begin to kick in. The loss causation requirement was intended to address that concern by providing a mechanism for dismissal in advance of discovery. *See, e.g.*, 141 Cong. Rec. S9032, 9040 (June 26, 1995) (statement of Senator Domenici) (PSLRA "stops fishing expeditions where lawyers can force thousands of dollars worth of discovery money and demand thousands of company documents before a judge can decide if the complaint really states a cause of action, so that it might be dismissed before the costs of discovery are ever incurred.").

The Ninth Circuit's loss causation standard – in conflict with the standard employed by numerous other federal appeals courts – virtually eliminates the possibility that security fraud lawsuits can be weeded out at the pleadings stage on the basis that the plaintiff has inadequately pleaded loss causation. Review is warranted to resolve that conflict.

II. The Ninth Circuit's Standard Is Particularly Hard on Firms, Such as Gilead, That Are Subject to Extensive Government Regulation

Review is also warranted because the Ninth Circuit's loss causation standard is particularly onerous for companies, such as Gilead, whose activities are

subject to close federal regulation. The Ninth Circuit's standard permits plaintiffs to transform virtually any regulatory infraction into a securities fraud case; all they need do is locate a stock price drop that followed disclosure of the infraction, and then allege that the disclosure caused the price drop.

The pharmaceutical and biotechnology industries are among the most heavily regulated industries in the United States. Gilead is not permitted to market any product to consumers without first obtaining marketing approval from FDA. The application for such approval is a multi-year process that can cost hundreds of millions of dollars. Once marketing begins, companies are subject to intense FDA scrutiny with respect to both their manufacturing practices and their marketing campaigns. As this case illustrates, when FDA officials take issue with one of those practices, they often send Warning Letters expressing their disagreement and threatening to take enforcement action if the practice continues.[5]

According to the Ninth Circuit, FDA's decision to send a Warning Letter to Gilead rendered plausible Respondents' entire theory of loss causation. The appeals court viewed the letter as a sufficient factual basis for Respondents' claims that: (1) Gilead's entire promotional campaign for Viread was in violation of federal food and drug laws; (2) doctors would not have engaged in the entirely legal practice of prescribing Viread for off-label uses but for the illegal promotion;

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[5] It is important to note, however, that the Warning Letter itself does not constitute enforcement action by the agency.

(3) doctors were apparently unaware that some of their Viread prescriptions were for off-label uses, because they supposedly became increasingly reluctant to write Viread prescriptions after learning of the Warning Letter; and (4) the stock price dropped on October 29, 2003 when it suddenly dawned on investors that the Warning Letter released three months earlier was causing doctors to change their views about Viread, even though no one was quoted as saying so in public. The complaint included absolutely no factual allegations to support any one of those four claims. But, from the Ninth Circuit's perspective, the fact that a federal regulatory agency had written a warning letter to the defendant rendered plausible each of those four otherwise unsubstantiated claims.

WLF urges the Court to grant review to make clear that the federal securities laws should not be extended in this manner. The Second Circuit has essentially held that the securities laws are appropriately used as an additional means of ensuring that pharmaceutical and biotechnology companies comply with food and drug laws. The Court warned against such expansion in *Stoneridge*. The plaintiffs in that case sought to hold companies liable for securities fraud under a "scheme liability" theory – even though the defendants had made no statements upon which the plaintiffs relied when investing in Charter Communication's common stock, which later decreased in value. The plaintiffs alleged that the defendants (companies that had engaged in arm's-length business transactions with Charter) had structured those transactions in a manner that assisted Charter in carrying out fraud. In refusing to extend securities

fraud liability to the defendants, the Court warned against expanding securities law so as to regulate the conduct of those not involved in the issuance and sale of securities. *Stoneridge*, 128 S. Ct. at 771. The Court said that § 10(b) "should not be interpreted to provide a private cause of action against the entire marketplace in which the issuing company operates." *Id.*

Similarly, the Court should not permit § 10(b) to serve as an alternative means of enforcing a publicly traded company's regulatory obligations. If FDA becomes convinced that Gilead has failed to comply with provisions of federal food and drug law, it is free to bring appropriate enforcement actions. But FDA's determination that one Gilead official has engaged in improper promotion of Viread does not provide any sort of basis for concluding that Gilead has defrauded its investors. It is possible, of course, that a biotechnology company's stockholders could suffer losses when exposure of a massive fraud committed by the company leads to a collapse of the price of its common stock. But the courts should not permit plaintiffs' lawyers to conflate evidence of such fraud with evidence of a single regulatory violation. Review is warranted to make clear that – contrary to the Ninth Circuit's holding – evidence of a single regulatory violation does not render plausible allegations that a public company's material misrepresentations caused the plaintiffs' loss.

III. This Case Is a Particularly Good Vehicle for Resolving the Question Presented, in Light of Its Status as a "Poster Child" for the Extreme Leniency of the Ninth Circuit's Standard

One look at the appendix to this brief should be sufficient to demonstrate the frivolousness of this lawsuit. The appendix includes a chart that illustrates the virtually uninterrupted rise in the price of Gilead common stock over the past decade.

The October 29, 2003 drop in stock price that is the subject of this lawsuit persisted for less than five weeks, and the initial complaint filed in this very complaint provides a very plausible explanation (an under-estimation of wholesalers' inventory levels) for that temporary blip. Respondents' far-fetched, alternative explanation for the temporary price drop should be laughed out of court. Instead, it survived the Ninth Circuit's loss causation standard with flying colors – thereby highlighting the need for immediate review of that standard.

At a minimum, a standard for evaluating the adequacy of loss causation allegations ought to require the plaintiff to plead a theory that: (1) accounts for the uncontested facts of record; and (2) demonstrates why it is likely that the drop in the defendant's stock price was attributable to the disclosure of the defendant's misrepresentations and not to other potential causes. *See Dura,* 544 U.S. at 342-43 ("When the purchaser subsequently resells such shares, even at a lower price, that lower price may reflect, not the earlier

misrepresentation, but changed economic circumstances, changed investor expectations, new industry-specific or firm-specific facts, conditions, or other events, which taken separately or together account for some or all of the lower price."). The Ninth Circuit applied a standard that examined neither of those factors. Had the Ninth Circuit done so (as would have been required under standards adopted by all other federal appeals courts that have examined the issue), the deficiencies in Respondents' loss causation theory would have been readily apparent.

As noted above, Respondents' loss causation theory fails to account for three uncontested facts. First, analysts in October 2003 all attributed the sales drop to inventory build-up (by the three wholesalers who purchase almost all of the products sold by Gilead). Analysts concluded that Gilead's sales dropped not as a result of a decrease in prescriptions being written for Viread, but because wholesalers during the third quarter were drawing down the inventory they had built up during the second quarter in anticipation of a previously announced June 2003 price increase for Viread.[6] The evidence indicates that the number of Viread prescriptions being written by doctors increased during the third quarter. Respondents' theory (which posits that sales dropped because doctors who had been writing off-label prescriptions all along suddenly became reluctant to do so because of a warning letter that said nothing derogatory about the safety or efficacy of

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[6] Analysts explained that third quarter Viread sales were lower than anticipated because the second-quarter inventory build-up had been larger than analysts had originally anticipated.

Viread), does not explain the facts regarding overstocking and increased prescriptions.

Second, there was virtually no discussion of FDA's Warning Letter in the days leading up to the October 29 price drop. The market did not react at all to the initial disclosure of the Warning Letter, which alleged that a single Gilead official had engaged in improper promotion of Viread on a single occasion. Respondents allege that Gilead's misconduct was far more widespread than the single incident that was the subject of the Warning Letter and that Gilead had misleadingly omitted mention of that misconduct. If so, there is no evidence to suggest that investors by October 29, 2003 had become aware of the allegedly widespread misconduct. In other words, even assuming the accuracy of Respondent's allegation that Gilead was engaged in a massive, illegal marketing campaign, Respondents have failed to provide any factual allegations supporting their contention that the investing public had come to understand that such a campaign existed.

Third, although Gilead stock dropped 12% on October 29, it immediately started to recover and by December 2, 2003 had returned to its October 28 price. Respondents have failed to provide any plausible explanation for that rapid increase in value. If, as Respondents allege, the market was finally aware by October 29 that a significant portion of Viread sales were being driven by Gilead's improper promotional activities and that the failure to disclose those activities had led to Gilead common stock being overpriced, there is no plausible explanation for the rapid subsequent

price rise. There is no reason to believe that market participants suddenly forgot that the stock had previously been overpriced. Yet, Respondents fail to provide any explanation, consistent with their theory of loss causation, that would rationally explain the rapid rise of Gilead stock between October 29 and December 2, 2003.

In sum, had the Ninth Circuit adopted a loss causation standard similar to the standard adopted by other circuits, it would quickly have realized that Respondent's loss causation theory was not even plausible. Review is warranted to determine whether a loss causation standard that fails to weed out claims as implausible as Respondents comports with the PSLRA and *Dura*.

CONCLUSION

Amicus curiae Washington Legal Foundation respectfully requests that the Court grant the petition for a writ of certiorari.

Respectfully submitted,

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Dated: March 16, 2009

APPENDIX

Print Historical Price Chart for Gilead Sciences Inc (GILD) - MSN Money

44.05 ▼ -1.38 -3.04%

Open: **45.45** High: **45.81** Low: **43.75**

Previous Close: **45.43** Volume: **4,165,753**

Eastern Time